K011349

OCT - 5 2001

Summary of Safety and Effectiveness for the Intercostal Lockable-Directable Port

Submitted by

Medcanica, Inc.
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Identification of a Legally Marketed Predicate Device

The ILDP is substantially equivalent to Diamond-Touch and Micro Diamond-Touch Instruments manufactured and marketed by the Deknatel Snowden-Pencer (Genzyme Corporation) pursuant to 510(k) K960400.

General Description

The ILDP is a non-toxic, sterile, single use, disposable surgical access port. The device is intended to be inserted percutaneously into the thoracic cavity to provide access for endoscopic instruments such as cutters, graspers, stabilizers, suture holders, etc.

The device incorporates a slit ball mechanism that permits the cannula to be precisely located with respect to the intended surgical site. Once the port has been located as desired it can be locked in place by a latching mechanism that compresses the slit ball, thus locking the port in place.

Intended Use

Intercostal Lockable-Directable Port has application in minimally invasive thoracic surgical procedures to establish a path of entry for minimally invasive surgical instruments. These procedures include Coronary Artery Bypass Grafting (CABG), Minimally Invasive Coronary Artery Bypass (MIDCAB), and Port Access Beating Heart Coronary Artery Bypass (POPCAB).

Summary of Technological Characteristics

The ILDP was compared to the predicate device using a 14 point comparison and found to be equivalent.

Summary of Performance Data

Performance of the device was established and compared to that of the predicate utilizing 4 tests. An additional 11 points of testing were performed on the ILDP determine performance. The tests demonstrated ILDP is substantially equivalent to Diamond-Touch and Micro Diamond-Touch Instruments manufactured and marketed by the Deknatel

Snowden-Pencer (Genzyme Corporation). The materials of the device have been carefully selected for their long history of biocompatibility. Tissue contact materials are tested in accordance with ISO 10993-1.

Since the ILDP meets the requirements of the stated standards and embodies technological characteristics essentially identical to those of the predicate device, we believe the device is safe and effective and that it performs as well as or better than the predicate device. The device has been designed and developed utilizing design control methods in compliance with the GMP. The ILDP will be manufactured per specifications and good manufacturing practices that ensure the device is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 5 2001

Ms. Christian L. Mazzola
President
c/o Al Weisenborn
Medcanica, Inc.
19526 East Lake Drive
Miami, FL 33015

Re: K011349
Trade Name: Intercostal Lockable-Directable Port
Regulation Number: 21 CFR 870.1390
Regulation Name: Trocar
Regulatory Class: II
Product Code: DRC
Dated: July 25, 2001
Received: July 26, 2001

Dear Ms. Mazzola:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

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510(k) Number (if known): K011349

Device Name: Intercostal Lockable-Directable Port

Indications for Use:

Intercostal Lockable-Directable Port has application in minimally invasive thoracic surgical procedures to establish a path of entry for minimally invasive surgical instruments. These procedures include Coronary Artery Bypass Grafting (CABG), Minimally Invasive Coronary Artery Bypass (MIDCAB), and Port Access Beating Heart Coronary Artery Bypass (POPCAB).

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K011349

Prescription Use_____ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)